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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,040	02/01/2002	David Michael Goldstein	R0038H-CON	3728

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ROCHE PALO ALTO LLC
3431 HILLVIEW AVENUE
PATENT DEPT., M/S A2-250
PALO ALTO, CA 94304

EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

12

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,040

Applicant(s)

GOLDSTEIN ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19-32 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 19-32 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16, 19-32 and 38 are pending in the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 4, 2003 has been entered.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining

claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 33 has been renumbered claim 38.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16, 19-32 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have added subject matter in claims 1, 2, 16 and 38 which does not have support in the specification or the originally filed claims. See, specifically, the definitions (q) and (r) of R^3 in claim 1, the (n) definition of R^3 in claim 2, the (f) definition of R^3 in claim 16 and the (q) and (r) definitions of R^3 in claim 38. Applicants state that support is found on pages 57, 59 and 72 of the specification. However, this showing is not persuasive. Enablement for a single compound cannot provide enablement for the breadth of claims sought in arts which are unpredictable. *Ex parte Hitzeman*, 9 USPQ2d 1821 (BPAI 1987). Therefore, the claims lack written description as such.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 12, 32 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faraci et al. {WO 94/13643}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim pyrazole products. Faraci et al. teach pyrazole products that are structurally similar to the instant claimed pyrazole products.

See in Faraci et al., for example, wherein A is $-C(=O)$, R_1 is amino, R_2 is alkyl, R_3 is phenyl substituted with a acetyl-alkyl group and R_4 is halophenyl (pages 1, 2 and 4). Also see, for example, the products on page 36, line 10; page 40, line 15; page 43, line 19; and page 44, lines 12-14.

Faraci et al. teach that the pyrazole products are useful in treating disorders such as inflammatory disorders and immune suppression (page 5, lines 1-12).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the products in the prior art and the instantly claimed products is that of generic description.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of “some” among “many” is *prima facie* obvious. The motivation to make the pyrazole products derives from the expectation that structurally similar products would possess similar activity (e.g., an anti-inflammatory).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating inflammatory disorders. The instant claimed invention would have been suggested to one skilled in the art and

therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicants' arguments filed March 4, 2003 have been fully considered. Applicants argue that the products embraced by newly added claim 38 do not overlap with Faraci et al. In response, there is an overlap of the products in Faraci et al. with the products of instant claim 38. See, for example, the compound on page 40, line 15 in Faraci et al. and the (k) definition of R^3 in claim 38.

Applicants argue that the specie found in Faraci et al. have a methylthio group at the 3-position of the pyrazole ring but the instant claimed products do not have a methylthio group at the 3-position of the pyrazole ring (the instant R^2 variable). Applicants argue that the use of a *per se* rule, such as *In re Lemin*, is improper for determining obviousness. Applicants further argue that looking at Faraci et al. as a whole, one in

the field looking at Faraci et al. would not have been motivated to identify the products instantly claimed.

All of Applicants' arguments have been considered but have not been found persuasive. It is well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art to person of ordinary skill in the art. *In re Boe*, 148 USPQ 507, 510 (CCPA 1966).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Applicants claim pyrazole products. Faraci et al. teach pyrazole products that are structurally similar to the instant claimed pyrazole

products. The difference between the products of Faraci et al. and the products instantly claimed is that some of the instant claimed products are generically embraced by the products of Faraci et al. Faraci et al. prepare specie which differ only at one position from the products instantly claimed or otherwise, the rejection of the claims would have been made under 35 USC § 102(b). Faraci et al. also teach that R² representing “ethyl” is a preferred embodiment (page 4, line 6). Applicants teach that their R² variable can be an alkyl group.

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating inflammatory disorders. Therefore, the instant claimed invention would have been obvious to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to

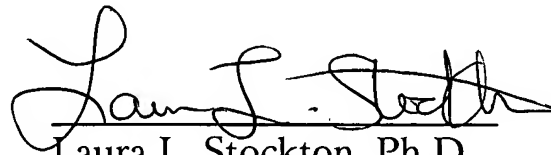
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2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

A handwritten signature in black ink, appearing to read 'Laura L. Stockton', written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

June 16, 2003